

PCT

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INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference IPB/129083		<b>FOR FURTHER ACTION</b> See Notification of Transmittal of International Preliminary Examination Report (Form PCT/PEA/416)	
International application No. PCT/DK 03/00470	International filing date (day/month/year) 03.07.2003	Priority date (day/month/year) 08.07.2002	
International Patent Classification (IPC) or both national classification and IPC A61L29/14			
Applicant COLOPLAST AS et al.			

1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.
2. This REPORT consists of a total of 7 sheets, including this cover sheet.  
  
☐ This report is also accompanied by ANNEXES, i.e. sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).  
  
 These annexes consist of a total of sheets.

3. This report contains indications relating to the following items:
  - I ☒ Basis of the opinion
  - II ☐ Priority
  - III ☐ Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
  - IV ☒ Lack of unity of invention
  - V ☒ Reasoned statement under Rule 66.2(a)(ii) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
  - VI ☐ Certain documents cited
  - VII ☐ Certain defects in the international application
  - VIII ☐ Certain observations on the international application

Date of submission of the demand  19.01.2004	Date of completion of this report  04.10.2004
Name and mailing address of the international preliminary examining authority:   European Patent Office D-80298 Munich Tel. +49 89 2399 - 0 Tx: 523656 epmu d Fax: +49 89 2399 - 4465	Authorized Officer  Staber, B  Telephone No. +49 89 2399-8587  

**INTERNATIONAL PRELIMINARY  
EXAMINATION REPORT**

International application No. PCT/DK 03/00470

**I. Basis of the report**

1. With regard to the elements of the international application (*Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report since they do not contain amendments (Rules 70.16 and 70.17)*):

**Description, Pages**

1-18 as originally filed

**Claims, Numbers**

1-22 as originally filed

**Drawings, Sheets**

1/1 as originally filed

2. With regard to the language, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.

These elements were available or furnished to this Authority in the following language: , which is:

- ☐ the language of a translation furnished for the purposes of the international search (under Rule 23.1(b)).
- ☐ the language of publication of the international application (under Rule 48.3(b)).
- ☐ the language of a translation furnished for the purposes of international preliminary examination (under Rule 55.2 and/or 55.3).

3. With regard to any nucleotide and/or amino acid sequence disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:

- ☐ contained in the international application in written form.
- ☐ filed together with the international application in computer readable form.
- ☐ furnished subsequently to this Authority in written form.
- ☐ furnished subsequently to this Authority in computer readable form.
- ☐ The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.
- ☐ The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.

4. The amendments have resulted in the cancellation of:

- ☐ the description, pages:
- ☐ the claims, Nos.:
- ☐ the drawings, sheets:

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5. ☐ This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed (Rule 70.2(c)).  
(Any replacement sheet containing such amendments must be referred to under item 1 and annexed to this report.)

6. Additional observations, if necessary:

**IV. Lack of unity of invention**

1. In response to the invitation to restrict or pay additional fees, the applicant has:

- ☐ restricted the claims.  
☐ paid additional fees.  
☐ paid additional fees under protest.  
☐ neither restricted nor paid additional fees.

2. ☒ This Authority found that the requirement of unity of invention is not complied with and chose, according to Rule 68.1, not to invite the applicant to restrict or pay additional fees.

3. This Authority considers that the requirement of unity of invention in accordance with Rules 13.1, 13.2 and 13.3 is

- ☐ complied with.  
☐ not complied with for the following reasons:

4. Consequently, the following parts of the international application were the subject of international preliminary examination in establishing this report:

- ☒ all parts.  
☐ the parts relating to claims Nos. .

**V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement**

1. Statement

Novelty (N)	Yes: Claims	4, 5, 9-11, 14-18, 20-22
	No: Claims	1-3, 6-8, 12, 13, 19
Inventive step (IS)	Yes: Claims	11, 14
	No: Claims	1-10, 12, 13, 15-22
Industrial applicability (IA)	Yes: Claims	1-22
	No: Claims	

2. Citations and explanations

see separate sheet

**INTERNATIONAL PRELIMINARY  
EXAMINATION REPORT - SEPARATE SHEET**

International application No. PCT/DK 03/00470

**Non-unity**

The present application contains two separate inventions which are not so linked as to form a single general inventive concept (Rule 13.1 PCT) for the following reasons:

The object of the first invention is to provide an external urinary catheter which is transparent (cf. p. 5, l. 9-13) having a certain degree of transparency as mentioned on page 6, lines 20 to 23.

The solution proposed is an external urinary catheter made from a material comprising at least one transparent thermoplastic elastomer and a plasticizer (cf. p.5, l. 25 -28) wherein the elastomer is represented by polystyrene-polyethylene/butylene- polystyrene compound, styrenic elastomer and metallocen polyethylene and polypropylene (cf. p.6, l. 11-16).

The first invention is defined by claims 1 (partly), 2 to 5, 9, 10, 12, 13 and 15 to 22.

The object of the second invention is to provide an external urinary catheter which is permeable, which allows the skin beneath to breathe (cf. p.5, l. 13-15) and which has a degree of breathability as defined on page 7, lines 13 to 19.

The solution proposed is an external urinary catheter made from a permeable thermoplastic elastomer and a plasticizer (cf. p.6, l. 24-27); the elastomer is a polyamide block copolymer, a polyether ester and a thermoplastic polyurethane (cf. p. 7, l. 20- 25).

The second invention is defined by claims 1 (partly), 6 to 14 and 15 to 22.

Since the present application deals with two different problems, namely transparency and permeability of an external urinary catheter, and suggests different solutions for said problems, the present invention lacks unity.

**Section V**

The following documents are taken into consideration:

- D1: US-A-5 376 085 (CONWAY PHILIP J ET AL) 27 December 1994 (1994-12-27)
- D2: EP-A-0 488 021 (TACTYL TECH INC) 3 June 1992 (1992-06-03)
- D3: EP-A-1 062 957 (DENKI KAGAKU KOGYO KK) 27 December 2000 (2000-12-27)
- D4: WO 91 17728 A (COLOPLAST AS) 28 November 1991 (1991-11-28) cited in

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the application

D5: WO 96 29962 A (MENTOR CORP) 3 October 1996 (1996-10-03)

D6: US-B1-6 221 447 (COHEN ROBERT E. ET AL) 24 April 2001 (2001-04-24)

D7: WO 96 08352 A (ANSELL PERRY INC ; JACKSON ANDREW PATRICK  
(GB)) 21 March 1996 (1996-03-21)

**1. Novelty of the first invention**

The first invention relates to an external urinary catheter having at least one area which is transparent.

D1 relates to an external urinary catheter made of silicone rubber which can be totally transparent (cf. D1, col. 5, l.33-36). D1 takes away novelty of claim 1 since the method of manufacturing the claimed catheter does not render the product per se novel over D1.

In addition D2 describes articles such as external urinary catheters which are made from elastomeric copolymers which are of the styrene ethylene/butylene - styrene type and which are used in combination with a plasticizer (cf. D2, col.3, l.2-14).

D2 destroys novelty of claims 1 to 3.

D3 is pertained to flexible, elastic and transparent medical device including a catheter (cf. D3. p.2, l.13) comprising a composition of styrene-ethylene random copolymer and a plasticizer to which further polymeric compounds can be added (cf. D3, p.2, l.54-58; p.3, l.25-28; p.8, l.34-52).

Said document takes away novelty of claims 1 to 3, 12 and 13.

Document D4 refers to an external urinary catheter which is manufactured by thermoplastic processing and which is based on polystyrene-polyethylene/butylene-polystyrene copolymers and process oil as plasticizer. The subject-matter of claims 1-3 and 19 is novelty destroyed by D4.

Hence, claims 1 to 3, 12, 13 and 19 are not novel in the sense of Article 33(2) PCT.

**2. Novelty of the second invention**

The second invention is concerned with an external urinary catheter which is permeable.

Document D5 describes an external urinary catheter of increased breathability which is made of a polyurethane sheet. Since as already mentioned the process of preparation does not necessarily impart novelty to the resulting product, document D5 anticipates the subject-matter of claims 1, 6, and 8.

D6 relates to catheters composed of a rubbery material, such as polyurethane elastomers (cf. D6, col. 2, l. 52 -67), and therefore takes away novelty of claims 1, 6 and 8.

D7 discloses articles including catheters (cf. D7, p. 9, l. 27-29) formed from a polyurethane emulsion containing a plasticizer via dip coating. Said document anticipates the subject matter of claims 1, 6 and 8.

Hence, claims 1, 6 and 8 do not fulfil the requirements of Art. 33(2) EPC.

### **3. Inventive Step**

The present invention provides an external urinary catheter which is transparent and/or permeable.

Transparent and/or permeable external urinary catheters are already described in D1, D3 and D5; these documents therefore represent the nearest prior art documents.

Concerning transparency, D1 and D3 teaches that a transparent external urinary catheter can be achieved by using silicone or a styrene copolymeric material. Since no information is given in the application that claimed thermoplastic elastomer in combination with a plasticizer and a slip additive exhibits a higher degree of transparency in comparison to the catheters mentioned in D1 and D3, the first invention of the present application does not involve an inventive merit.

Concerning the permeability, document D5 suggests to use polyurethane as material for the catheter.

The application shows that an advantageous material for an external urinary catheter is polyamide-polyether block copolymer blended with a terpolymer and a citrate plasticizer (as set out in claims 11 and 14) with regard to the permeability thereof. Such a material is regarded as a non-obvious alternative to polyurethane which may impart inventivity to the present invention.